BEFORE THE DEPARTMENT OF PUBLIC HEALTH AND HUMAN SERVICES OF THE STATE OF MONTANA

In the matter of the amendment of) N	NOTICE OF PUBLIC HEARING ON
ARM 37.112.103, 37.112.108,)	PROPOSED AMENDMENT
37.112.109, 37.112.116, 37.112.117,)	
37.112.131, 37.112.133, 37.112.137, 37.112.142, 37.112.144, 37.112.147, 37.112.158, 37.112.159, and)	
)	
)	
37.112.167 pertaining to body art and)	
cosmetics)	

TO: All Concerned Persons

- 1. On November 28, 2012, at 3:00 p.m., the Department of Public Health and Human Services will hold a public hearing in the auditorium of the Department of Public Health and Human Services Building, 111 North Sanders, Helena, Montana, to consider the proposed amendment of the above-stated rules.
- 2. The Department of Public Health and Human Services will make reasonable accommodations for persons with disabilities who wish to participate in this rulemaking process or need an alternative accessible format of this notice. If you require an accommodation, contact Department of Public Health and Human Services no later than 5:00 p.m. on November 21, 2012, to advise us of the nature of the accommodation that you need. Please contact Kenneth Mordan, Department of Public Health and Human Services, Office of Legal Affairs, P.O. Box 4210, Helena, Montana, 59604-4210; telephone (406) 444-4094; fax (406) 444-9744; or e-mail dphhslegal@mt.gov.
- 3. The rules as proposed to be amended provide as follows, new matter underlined, deleted matter interlined:
 - <u>37.112.103 DEFINITIONS</u> (1) through (4) remain the same.
- (5) "Body modification" is the intentional altering of the human body for any nonmedical reason.
 - (5) through (9) remain the same, but are renumbered (6) through (10).
- (10) (11) "Disinfectant" means a substance or solution, registered with the United States Environmental Protection Agency (EPA), that which kills or inactivates viruses and pathogenic microorganisms, but not necessarily their spores.
 - (11) remains the same, but is renumbered (12).
- (13) "Easily cleanable" means a characteristic of a surface that allows effective removal of soil by normal cleaning methods.
 - (12) remains the same, but is renumbered (14).
- (15) "Implant" means an artificial object inserted into a person's body. Implants do not include microdermal anchors or two-point piercings.
 - (13) through (16) remain the same, but are renumbered (16) through (19).

- (20) "Microdermal anchor" means a piece of jewelry defined in ARM 37.112.103(16) used for single-point piercings that has a foot no larger than 8mm in length.
 - (17) through (21) remain the same, but are renumbered (21) through (25).
- (22) (26) "Sharps" means any discarded instrument or article that may be contaminated with blood or other bodily fluid and may cause punctures or cuts, including but not limited to needles, scalpel blades, uncovered razors, and broken glass. A disposable shaving razor with protective cap in place is not considered a sharp.
- (27) "Single-point piercing" means a piercing that creates a hole in the skin that acts as both the entry and exit for a microdermal or transdermal anchor.
 - (23) through (27) remain the same, but are renumbered (28) through (32).
- (33) "Transdermal anchor" means a piece of jewelry defined under ARM 37.112.103(16) used for single-point piercings that has a foot larger than 8mm in length.
- (34) "Two-point piercing" means a piercing that punctures the skin creating a distinct entry and exit point.
 - (28) and (29) remain the same, but are renumbered (35) and (36).

AUTH: <u>50-48-103</u>, MCA

IMP: 50-48-102, <u>50-48-103</u>, MCA

- 37.112.108 GENERAL FACILITY REQUIREMENTS (1) Work rooms, cleaning rooms, restrooms, handwashing facilities, waiting areas, and all establishment areas to which clients have access must be kept clean and free of garbage, litter, unnecessary articles, dust, dirt, and sources of airborne dust or fumes.
 - (2) through (4) remain the same.

AUTH: <u>50-48-103</u>, MCA IMP: <u>50-48-103</u>, MCA

37.112.109 WATER SUPPLY (1) remains the same.

- (2) Before a license may be issued, an establishment using an individual, shared, or multiple user water supply must submit the following to the department or its designee:
- (a) satisfactory coliform bacteria and nitrate test results as specified in ARM Title 37 17, chapter 38, subchapter 2; and
 - (b) remains the same.
- (3) A supplier of an individual, shared, or multiple user water supply shall must conduct a coliform bacteria test of the system at least twice a year with one sample collected between April 1 through June 30 and the second sample collected between August 1 through October 31, and shall must conduct a nitrate test of the system at least once every three years. Water tests must be analyzed at a certified laboratory. A supplier shall must keep sampling result records for at least three years.
 - (4) through (8) remain the same.

(9) Bottled and packaged potable water must be obtained from a licensed and approved source and shall <u>must</u> be handled and stored in a way that protects it from contamination.

AUTH: <u>50-48-103</u>, MCA IMP: <u>50-48-103</u>, MCA

- <u>37.112.116 TOILETS AND HANDWASHING FACILITIES</u> (1) and (2) remain the same.
- (3) The toilet room must be <u>ventilated</u> vented to the outside, well lit, and equipped with a self-closing door, toilet tissue, and waste receptacle.
 - (4) through (9) remain the same.
 - (10) Soap must be conveniently located to the handwashing sink.
- (11) Single-use towels Each handwashing sink must be provided with individual, disposable towels that are kept clean must be conveniently located for drying hands and a waste receptacle.

AUTH: <u>50-48-103</u>, MCA IMP: <u>50-48-103</u>, MCA

- 37.112.117 WORK ROOM REQUIREMENTS (1) through (5) remain the same.
- (6) The work room must have adequate ventilation. If heating ducts, vents, or air conditioners discharge into the work room, the intakes for such venting must be filtered, and the filters must be maintained to minimize airborne dust and insects.
 - (7) remains the same.
- (8) The work rooms must have a handwashing facility unless there is <u>a</u> handwashing facility outside the work room within ten feet of the work room door.
 - (a) remains the same.
 - (b) The handwashing station cannot be in the same room as the toilet.
 - (b) through (g) remain the same, but are renumbered (c) through (h).
- (h) (i) Single-use towels Individual, disposable towels must be conveniently located for drying hands.
 - (9) through (10) remain the same.
- (11) The floor of the work room must be constructed of smooth and impervious materials and that are easily cleanable and in good condition. The floor must be wet-mopped daily.
 - (12) remains the same.

AUTH: <u>50-48-103</u>, MCA IMP: <u>50-48-103</u>, MCA

- <u>37.112.131 STERILIZATION OF EQUIPMENT AND JEWELRY</u> (1) remains the same.
- (2) All jewelry must be sterilized or disinfected by at least one of the following methods:
 - (a) individually wrapped and autoclaved; or

- (b) come from the supplier individually wrapped and sterile; or.
- (c) be disinfected by complete immersion in 70% alcohol.
- (3) Whenever an autoclave is used, the following requirements apply:
- (a) Autoclave packaging and a testing indicator for verifying temperatures must be used each time <u>the autoclave is used</u>.
 - (b) and (c) remain the same.
- (d) Monthly biological monitoring must be conducted on the autoclave using standard spore units that are analyzed by a certified laboratory. The results of the testing must be provided to the health authority on a monthly basis and the monthly spore test must be posted in a conspicuous place.
- (e) In the event of a failed spore test, the operator must immediately cease use of the autoclave and contact the health authority within one business day.
 - (e) remains the same, but is reunumbered (f).
 - (4) remains the same.
- (5) Jewelry that is sterilized by a chemical sterilant using 70% alcohol for 10 minutes must be immediately inserted into the client to prevent possible contamination.

AUTH: <u>50-48-103</u>, MCA IMP: 50-48-103, MCA

37.112.133 SKIN PREPARATION, ASEPTIC TECHNIQUE, AND AFTERCARE (1) remains the same.

- (2) At all times during the tattooing or body piercing procedure, artists shall must use sterile instruments as specified in ARM 37.112.131 and aseptic techniques.
- (3) Before and after performing the tattooing or body piercing procedure, artists shall <u>must</u> thoroughly wash their hands, <u>and</u> wrists, <u>and lower arms</u> in warm running water with soap for at least 20 seconds, scrubbing around and under their fingernails, rinsing completely, and drying with a clean, <u>single-use towel</u> <u>individual</u>, disposable towels.
- (4) Artists shall <u>must</u> wear a clean outer garment. A hair restraint must be worn if necessary to prevent the artist's hair from contact with the client. All necklaces, bracelets, or other personal items of the artist either must be removed or covered by the outer garment or sterile gloves to prevent the item coming in contact with the client.
- (5) If it is necessary to shave the client's skin area to be tattooed or pierced, the artist shall must use single-use razors. Straight razors, electric razors, and replaceable blade units may not be used. After shaving the client's skin, the artist shall must:
 - (a) and (b) remain the same.
- (6) If the artist wore gloves to wash or shave the client's skin, the artist shall must discard those gloves after completing those tasks. The artist shall must then put on a new pair of gloves before continuing the procedure.
 - (7) remains the same.
- (8) If it is necessary to use a marking device, the marking device must be used only once. If it is necessary to use a marking device, the tip of the marking

<u>device must be vigorously wiped with 70% alcohol or other approved disinfectant before and after use, or used only once.</u>

- (9) remains the same.
- (10) If the artist's gloved hands become contaminated during the tattooing or body piercing procedure, then the artist shall must rewash hands and reglove before resuming the procedure.
 - (a) remains the same.
- (b) If the artist sustains a needle stick, the artist shall must resume the tattooing or body piecing piecing procedure with clean and sterile equipment after rewashing hands and regloving.
 - (11) remains the same.
- (12) Upon completion of the tattooing or piercing procedure, artists shall must apply an antiseptic solution to the procedure area with a clean single-use cotton ball, gauze, or tissue.

AUTH: <u>50-48-103</u>, MCA IMP: <u>50-48-103</u>, MCA

37.112.137 HANDLING AND DISPOSAL OF INFECTIOUS MATERIAL

- (1) Waste that may have been contaminated with blood or body fluids must be separated from other waste in different and stored in a containers with a biohazard warning label.
- (2) An adequate supply of sharps containers must be maintained on the premises. A sharps container must:
- (a) be leakproof, rigid, and strong enough to protect the handler and others from accidental cuts or puncture wounds; and
- (b) be closed or capped securely to prevent the loss of contents for disposal-; and
 - (c) not be filled more than 3/4 full.
 - (3) remains the same.
- (4) An artist shall <u>must</u> use adequate protections, such as a brush, dust pan, or tongs to pick up any broken glassware in the work room. After engaging in such cleaning, the artist shall <u>must</u> wash hands and reglove as described in ARM 37.112.133 before working with a client.
 - (5) and (6) remain the same.

AUTH: <u>50-48-103</u>, MCA IMP: 50-48-103, MCA

- <u>37.112.142 CLIENT RECORD</u> (1) The operator must maintain a client record for each client. At a minimum, the client record must include:
 - (a) and (b) remain the same.
 - (c) the address, and telephone number, and name of the establishment;
 - (d) and (e) remain the same.

AUTH: <u>50-48-103</u>, MCA IMP: <u>50-48-103</u>, MCA

37.112.144 CONSENT FORM (1) remains the same.

- (2) The consent form must contain:
- (a) remains the same.
- (b) a description of potential complications and side-effects, including abscesses, allergies, excessive bleeding (from body piercing), heavy metal poisoning, infection, keloid formation, muscle paralysis, nerve paralysis, scarring, swelling, blood-borne pathogens, tongue swelling, throat closure, and tooth fracture (from oral piercing).
 - (c) remains the same.
- (d) instructions to consult a physician <u>licensed medical provider</u> if symptoms of infection or other complications occur;
 - (e) remains the same.
 - (f) a statement by the client that the client:
- (i) has been provided with the preservice information aftercare instructions, both in writing and verbally by the artist; and
 - (ii) remains the same.

AUTH: <u>50-48-103</u>, MCA IMP: 50-48-103, MCA

- <u>37.112.147 TRAINING</u> (1) Operators and artists shall <u>must</u> complete formal training provided by the department or its designee that includes at least general sanitation, first aid, and universal precautions for preventing the transmission of blood-borne pathogens before licensure.
- (2) Operators shall complete formal training within one year prior to obtaining a license from the department, and at least once in each calendar year of license renewal thereafter. Artists shall complete formal training within 60 days of hire, contract, or apprenticeship with an operator, and at least once every calendar year thereafter. Operators and artists must maintain current training certification with approved providers for first aid, and universal precautions for preventing the transmission of blood-borne pathogens and follow certifying organizations guidelines for expiration and renewal.
- (3) Guest artists and new artists must complete formal training and provide the inspecting authority with documentation of this training prior to working in a licensed facility. Guest artists must also provide documentation of experience to the body art health authority in the jurisdiction they wish to work.
 - (3) and (4) remain the same, but are renumbered (4) and (5).

AUTH: <u>50-48-103</u>, MCA IMP: <u>50-48-103</u>, MCA

- <u>37.112.158 RESTRICTIONS AND PROHIBITIONS</u> (1) A tattooing or body piercing procedure may not occur if:
- (a) either the artist of <u>or</u> the client is under the apparent influence of alcohol or other mind-altering drugs;
 - (b) through (4) remain the same.

AUTH: <u>50-48-103</u>, MCA IMP: <u>50-48-103</u>, MCA

<u>37.112.159 VARIANCE</u> (1) A licensee may request a variance to waive or modify compliance with the health requirements of this <u>sub</u>chapter by petitioning the department. An application for a variance must contain:

- (a) through (2) remain the same.
- (3) A licensee must continuously demonstrate compliance with the variance or modification granted by the department. The failure to comply to the department-approved variance or modification may be grounds for license revocation. The failure to continuously demonstrate compliance with a variance or modification may result in license revocation or nonvalidation.
 - (4) remains the same.

AUTH: 50-48-103, MCA

IMP: 50-48-103, <u>50-48-204</u>, MCA

<u>37.112.167 BODY PIERCING: EAR LOBE PIERCING EXEMPTIONS</u>

- (1) Establishments that perform ear lobe piercing only by using a mechanized presteralized ear-piercing system approved by the department or its designee may be exempted from ARM 37.112.116(2), 37.112.117(2), (5), and (8) as long as:
 - (a) and (b) remain the same.
- (c) the artist and client must have convenient access to handwashing facilities. If the handwashing facility is not within the work room or within ten feet of the work room door, then an 70% alcohol-based hand sanitizer must be used in accordance with the U.S. Centers for Disease Control "Guideline for Hand Hygiene in Health-Care Settings" (Morbidity and Mortality Weekly Reports, 2002, Vol. 51, No. RR-16) immediately before putting on gloves and immediately after removal of the gloves. The department hereby adopts and incorporates by reference the U.S. Centers for Disease Control "Guideline for Hand Hygiene in Health-Care Settings" (Morbidity and Mortality Weekly Reports, 2002, Vol. 51, No. RR-16). Copies of this guideline may be obtained by contacting the Montana Department of Public Health and Human Services, Public Health and Safety Division, Food and Consumer Safety Section, 1400 Broadway, P.O. Box 202951, Helena, MT 59620-2951.

AUTH: <u>50-48-103</u>, MCA IMP: <u>50-48-103</u>, MCA

4. STATEMENT OF REASONABLE NECESSITY

The Department of Public Health and Human Services (the department) is proposing amendments to the body art rules to more accurately represent the purpose and intent of the rule. Many of the proposed amendments are simple clarifications, grammatical errors, or internal inconsistencies. There are some substantive changes that are specifically outlined below.

ARM 37.112.103

The department is proposing to amend and add new definitions to clearly explain terms used in these rules.

ARM 37.112.108

The department is proposing to add language to (1) to prevent cleaning rooms from becoming dirty or accumulating garbage or dust.

ARM 37.112.109

The department is proposing to correct an ARM title number and make grammatical changes to ensure the rule is consistent using the word "must."

ARM 37.112.116

The department is proposing to add language to (3) to make the toilet and handwashing facility requirements more attainable for new businesses while ensuring health standards are still met; and amend (11) to clarify the language regarding hand drying towels at the handwashing sink.

ARM 37.112.117

The department is proposing to remove language from (6) to create a more general statement about ventilation while still maintaining basic health standards; add language to (8) to make it clear that the handwashing sink used during a body art procedure cannot be in the same room as the toilet; change language in (8)(h) to standardize rule language within the department regarding the use of disposable towels in handwashing; and add language to (11) to ensure health standards are met regarding flooring in work areas.

ARM 37.112.131

The department is proposing to remove language from (2) to reflect the industry standard and bring the rule up to current health standards; add language to (3)(a) to clarify when a testing indicator should be used with the autoclave; add language to (3)(d) to ensure that autoclaves being used in body art facilities pass their monthly spore tests; and remove (5) to reflect the changes proposed in (2).

<u>ARM 37.112.133</u>

The department is proposing to add wording to (3) to reflect current handwashing standards; add wording to (5) because electric razors cannot be cleaned adequately between clients to meet hygienic standards; revise the wording of (8) to allow the

reuse of marking devices if they are disinfected properly between uses; and revise the wording of (9)(b) to correct a spelling mistake changing "piecing" to "piercing".

ARM 37.112.137

The department is proposing to add new language to clarify the contents of a sharps container and change the wording of (1) to clarify the intention of this section of the rule.

ARM 37.112.142

The department is proposing to add wording to (1)(c) to ensure that the name of the establishment is included on all approved consent forms.

ARM 37.112.144

The department is proposing to add wording to (2)(b) to include hepatitis, AIDS, other blood-borne pathogens, tongue swelling, and throat closure to the list of potential complications and side effects on the consent form; change the wording to (2)(d) from physician to licensed medical provider to more accurately reflect who should be contacted in case symptoms of infection occur as a result of a body art procedure; and change the wording to (2)(i) to more accurately reflect the accepted language used by industry professionals.

ARM 37.112.147

The department is proposing language that will ensure that any piercer or tattooist working legally in the state of Montana has met basic first aid, blood-borne pathogen, and general sanitation training requirements before they begin working.

The department is proposing to change the training requirements in (2) so that the department's training renewal requirements reflect those of the training providers.

<u>ARM 37.112.158</u>

The department is proposing to change the wording of (1)(a) from "of" to "or" to reflect a spelling mistake that was made.

ARM 37.112.159

The department is proposing to change the wording of (3) to clarify and more accurately reflect the results of failing to comply with a granted variance.

ARM 37.112.167

The department is proposing to add the wording "70%" to (1)(c) because this concentration of alcohol-based hand sanitizer has been shown to be the best for inactivation of microorganisms.

- 5. Concerned persons may submit their data, views, or arguments either orally or in writing at the hearing. Written data, views, or arguments may also be submitted to: Kenneth Mordan, Department of Public Health and Human Services, Office of Legal Affairs, P.O. Box 4210, Helena, Montana, 59604-4210; fax (406) 444-9744; or e-mail dphhslegal@mt.gov, and must be received no later than 5:00 p.m., December 6, 2012.
- 6. The Office of Legal Affairs, Department of Public Health and Human Services, has been designated to preside over and conduct this hearing.
- 7. The department maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by this agency. Persons who wish to have their name added to the list shall make a written request that includes the name, e-mail, and mailing address of the person to receive notices and specifies for which program the person wishes to receive notices. Notices will be sent by e-mail unless a mailing preference is noted in the request. Such written request may be mailed or delivered to the contact person in 5 above or may be made by completing a request form at any rules hearing held by the department.
- 8. An electronic copy of this proposal notice is available through the Secretary of State's web site at http://sos.mt.gov/ARM/Register. The Secretary of State strives to make the electronic copy of the notice conform to the official version of the notice, as printed in the Montana Administrative Register, but advises all concerned persons that in the event of a discrepancy between the official printed text of the notice and the electronic version of the notice, only the official printed text will be considered. In addition, although the Secretary of State works to keep its web site accessible at all times, concerned persons should be aware that the web site may be unavailable during some periods, due to system maintenance or technical problems.
 - 9. The bill sponsor contact requirements of 2-4-302, MCA, do not apply.

/s/ Shannon L. McDonald

Rule Reviewer

Anna Whiting Sorrell, Director

Public Health and Human Services

Certified to the Secretary of State October 29, 2012